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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,754	08/28/2001	Michele A. McTigue	0125-0016D3	3837

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AGOURON PHARMACEUTICALS, INC.  
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EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
1637	10

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/939,754	MCTIGUE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Young J. Kim	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 17-26 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) 17-26 is/are rejected.

7) Claim(s) 17,22 and 23 is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 13 November 2001 is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> .	6) <input type="checkbox"/> Other: ____.

**DETAILED ACTION**

***Claim Objections***

Claims 17, 22, and 23 are objected to because of the following informalities:

Claims 17, 22, and 22 recite the acronyms, "RTK," "PDGFR," and "VEGFR," respectively, without first identifying them. Amending the claim to recite the phrase, "Receptor Tyrosine Kinase," "Platelet Derived Growth Factor Receptor," and "Vascular Endothelial Growth Factor Receptor," respectively, would obviate this objection.

Claim 23 appears to contain a typographical error, "VEFGR." It is believed that the term should be, "VEGFR."

Appropriate corrections are required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is indefinite for the recitation of the phrase, "generate a model of said RTK polypeptide *suitable* for use in designing molecules that will act as agonists or antagonists to said polypeptide," because the claims do not set forth clear limitations of what aspects of the compound are to be considered when determining the suitability of the molecules.

Claim 17 is indefinite for the recitation of the phrase, "in designing molecules that will act as agonists or antagonist," in sub-step (c) because the preamble recites the method as being for screening **compounds**. The term usage is inconsistent with that of the preamble.

Claim 17 recites the limitation "said RTK polypeptide" in sub-step (c). There is insufficient antecedent basis for this limitation in the claim, rendering the claim confusing as to whether the method involves another RTK polypeptide. Amending the claim to recite, "said modified RTK polypeptide," would overcome this rejection.

Claim 17 recites the limitation "said polypeptide" in sub-step (c). There is insufficient antecedent basis for this limitation in the claim. Amending the claim to recite, "said modified RTK polypeptide," would overcome this rejection.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17, 25, and 26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9, 10, and 11 (respectively) of copending Application No. 09/939,833 (hereon referred to as '833 application). Although the

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conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. The corresponding U.S. Pre-grant Publication, US 2002/0164641 A1 is attached hereto.

Claim 17 of the instant application is drawn to a method of screening compounds suitable as RTK agonists or antagonists via computerized crystallography. Claim 17 further defines the RTK as having a kinase domain a helix D linked to RTK kinase domain a helix E by a truncated RTK kinase domain (KID). Claims 25 and 26 further limit the above claim to the RTK as being VEGFR-2 and an embodiment drawn to the RTK polypeptide comprising SEQ ID Number 5.

Claim 9 of the '833 application is drawn to the same method of screening for compound suitable for RTK agonists or antagonists via computerized crystallography. While the claim does not specifically recite the modified RTK polypeptide structure (e.g., helix D linking to helix E via truncated KID), the specification of the '833 application discloses the above limitation as the only working embodiment (see page 9, [84]). Claim 10 of the '833 application recites the same method as claim 9, except that it is drawn to a VEGFR-2, (claim 25 of the instant application). Claim 11 of the '833 application recites the specific mutation defined by SEQ ID Number 5 (claim 26 of the instant application). For the above reasons, the claims of the instant application is obvious over the claims of '833 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims allowed.

The prior art does not teach or reasonably suggest the modified RTK with the truncated KID domain, having a kinase activity, and the claimed method of use.

*Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

6/25/03

*Jeffrey Siew*  
JEFFREY SIEW  
PRIMARY EXAMINER  
6/29/03